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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/482,688 01/13/00 GARDINER P 23925-4

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EXAMINER

WILLIAMS, P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 04/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/482,688

Applicant(s)

GARDINER ET AL.

Examiner

Pernell V. Williams

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

Art Unit: 1616

DETAILED ACTION

Claims 1-57 are presented and available for examination.

Specification

1. The use of the trademarks and trade names WPI 97, Whey Peptides, WPC 80, and ION EXCHANGE has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1, 4, 6-11, 13, 25, and 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 6-8, 11-15, 17, and 20 of copending Application No. 09/420,439. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or

Art Unit: 1616

discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the absence of a distinct structural core or chemical formula, the identity of the "substance" instantly claimed is not seen to be distinctly claimed or particularly pointed out. Likewise, in the absence of a distinct origin or precursor, chemical core or formula, the identity of said "source" as instantly claimed is not seen to be distinctly claimed or particularly pointed out. In all occurrences wherein the terms "substance" and "source"

Art Unit: 1616

are not distinctly claimed or particularly pointed out, claims containing same are rendered indefinite.

Applicant's claim to "substance which can enhance and/or mimic insulin activity" is seen to assert that said substance must be both inclusive of both descriptive qualities, and simultaneously exclusive to only one descriptive quality. Cited claims therefore fail to distinctly claim and point out a substance which is instantly claimed, because by definition no single distinct substance is simultaneously inclusive and exclusive to any single distinct descriptive quality.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "comprises" in claims 20 and 53 is used by the claims to mean "has a mass of," while the accepted meaning is "includes." Also, the term "administering" in claims 25, 28, 32, 34, 37, 41, 43, 46, 50, and 52 is used by the claim to mean "adding," while the accepted meaning is "applying as a remedy." Said accepted meaning is transitive, with the subject in need of said remedy, not the tool for effecting said remedy, being the object of the "administering."

Claims 13 and 15-16 contain the trademarks/trade names WPI 97, Whey Peptides, WPC 80, and ION EXCHANGE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since

Art Unit: 1616

the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe sources of amino acids which appear to be whey-derived and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

4. Claims 1, 4, 6-11, 13, 25, and 34 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The cited claims of the instant application are also seen to be invented by the inventors in copending U.S. patent application 09/420,439.

Art Unit: 1616

5. Claims 1, 4, 6-11, 13, 25, and 34 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/420,439 ('439) which has a common inventor with the instant application.

Based upon the shared effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

6. Claims 1, 4, 6-11, 13, 25, and 34 are directed to the same invention as that of claims 1, 6-8, 11-15, 17, and 20 of commonly assigned copending Application '439. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the

Art Unit: 1616

basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as commonly assigned copending Application '439 at the time this invention was made. Accordingly, commonly assigned copending Application '439 is disqualified as prior art through 35 U.S.C. 102(f) or (g) in any rejection under 35 U.S.C. 103(a) in this application. However, this applied art additionally qualifies as prior art under subsection (f) of 35 U.S.C. 102 and accordingly is not disqualified as prior art under 35 U.S.C. 103(a).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1616

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of U.S. Patent 5,902,829 (Schneider *et al.*), and U.S. Patent 5,324,656 (Ham *et al.*).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Determining the scope and contents of the prior art

In Schneider *et al.*, the prior art compositional components are disclosed as follows:

- L-arginine (column 4 lines 50-60),
- A carbohydrate source (column 4 lines 9-15),
- Whey (column 4 lines 15-18), and
- Folic acid (column 4 lines 22-26).

In Ham *et al.*, the following components are disclosed as cell growth enhancing formulations:

- L-arginine (column 4 lines 6-12 and table 1),
- Myo-inositol (column 4 lines 6-12 and table 1),

Art Unit: 1616

- L-glutamine (column 4 table 1)
- L-phenylalanine (column 4 table 1)
- Folinic acid (column 4 table 1)

Ascertaining the differences between the prior art and the claims at issue

The instant application claims as essential components for a nutritional supplement a substance which increases nitric oxide production and a source of amino acids. The prior art compositions contain more components than those which applicant instantly claims as part of the instantly claimed compositions of matter. Prior art compositions contain components applicant claims as useful in a supplement, however prior art includes components for different reasons. Nonetheless, the components are disclosed as useful in supplements, rendering compositions comprised of same obvious.

Resolving the level of ordinary skill in the pertinent art

It would have been obvious to the practitioner of ordinary skill in this art at the time the invention was made to include in a single formulation, composition, or supplement a substance capable of increasing nitric oxide production in the body and a source of amino acid because, like the instant application, Schneider *et al.* and Ham *et al.* are seen to be in the same field of endeavor, which is the art of nutritional supplementation for human cells. The prior art's disclosure of the composition's ingredients for inclusion in compositions for nutritional formulations as set forth in the Schneider *et al.* patent and

Art Unit: 1616

as nutritional formulations as set forth in the Ham *et al.* patent as cellular growth media for human muscle cells, provides sufficient motivation to combine components to augment cellular maintenance and growth, particularly muscle cells, as applicant has done with the above cited references before them. Said assertion is particularly obvious when said substance capable of increasing nitric oxide production in the body is selected from the group of folic acid or folinic acid, L-arginine, and a carbohydrate source such as inositol, and said source of amino acid is selected from the group of L-arginine, whey, L-glutamine, and L-phenylalanine.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It is noted that there has not been presented any convincing evidence of record to obviate the rejection cited *supra*. In the absence of said evidence, the disclosures of the components as set forth in the prior art patents are seen to render the instantly claimed composition *prima facie* obvious.

8. Claims 2, 3, 5, 12, 19-24, 26-27, 34-36, 38-39, and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 5, 13, 14-16, 17, and 20 of copending Application No. 09/420,439 ('439). Although the conflicting claims are not identical, they are not

Art Unit: 1616

patentably distinct from each other because the instantly claimed compositions and methods share overlapping components with copending Application No. 09/420,439.

Claims 2, 3, 5, and 12 share overlapping composition components with analogous claims 2, 3, 13, and 14, listed respectively, from copending Application '439.

Claims 19-24, 26-27, 34-36, 38-39, and 44-45 are analogous with claims 14-16, 17, 20, 20, and 17, from copending Application '439. Compositions instantly set forth in claims 19-24 are directed to food supplements comprising glycosidal saponins, myo-inositol, d-chiro-inositol glucomannan, and a source of amino acids, which are the same components in claims 14-16 of copending Application '439. Methods instantly claimed in claims 26-27 are directed to supplementing a diet with a composition comprising substances which increase nitric oxide production in the body, and a source of amino acids, both of which are the analogous components in claim 17 of copending Application '439, rendering the instant claims provisionally obvious. Methods instantly claimed in claims 34-36 are directed to increasing muscle mass by supplementing a diet with a composition comprising substances which increase nitric oxide production in the body, and a source of amino acids, both of which are components of the same type in claim 20 of copending Application '439, rendering the instant claims provisionally obvious. Methods instantly claimed in claims 38-39 are directed to increasing muscle mass by supplementing a diet with a composition comprising substances which enhance or mimic insulin activity, and a source of amino acids, both of which are components of the same type in claim 20 of copending Application '439, rendering the

Art Unit: 1616

instant claims provisionally obvious. Methods instantly claimed in claims 44-45 are directed to supplementing a diet with a composition comprising substances which increase nitric oxide production in the body, and a source of amino acids, both of which are analogous to components in claim 17 of copending Application '439, rendering the instant claims provisionally obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


Claims 1-57 are not allowed at this time.

Art Unit: 1616

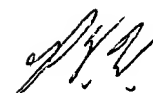
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pernell V. Williams, whose telephone number is (703) 308-4645. The examiner can normally be reached from 8AM to 4:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



James O. Wilson
Primary Examiner
Art Unit 1623



pwv
April 7, 2000